K093590

510K) SUMMARY

DATE
November 13, 2009

MAY 12 2010

PRODUCT, CLASSIFICATION NAME
Trade name: Planmeca Promax 3D Max
Common name: Tomography x-ray system
Classification: 76 EHD, Class II
Regulation number: 872.1800

MANUFACTURER
Planmeca Oy
Asentajankatu 6
FI-00880 Helsinki, Finland
Phone: +358 20 7795 500
Fax: +358 20 7795 396
Contact person: Lars Moring

UNITED STATES SALES REPRESENTATIVE (U.S. DESIGNATED AGENT)
Planmeca USA Inc.
100 North Gary Avenue, Suite A
Roselle, IL 60172
Phone: (630) 529 2300
Fax: (630) 529 1929
Contact person : Bob Pienkowski

INTENDED USE
Planmeca Promax 3D Max, is a three dimensional Cone Beam Volumetric Tomography (CBVT) x-ray system, which is intended to produce three-dimensional images of the human teeth, jaw and skull. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. The device is to be operated and used by dentists and other legally qualified health care professionals.

PRODUCT DESCRIPTION
The Planmeca Promax 3D Max is in principle a conventional digital panoramic/tomography x-ray system with three-dimensional Cone Beam Volumetric Tomography (CBVT) system add on. The product rotates around the patient and takes still images with a flat panel sensor synchronized to x-ray generator pulsing. A 3D reconstruction engine calculates the cylindrical 3-dimensional volume image, which then is viewed in 3D viewing stations.

SUBSTANTIAL EQUIVALENCE

We consider this product modification to be similar in design, composition and function to the following device introduced into commercial distribution after May 28, 1976:

K060328 Planmeca ProMax 3D

The comparison of characteristics supports substantial equivalence. Planmeca Promax 3D Max is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAY 12 2010

Mr. Lars Moring
Regulatory Affairs Manager
Planmeca Oy
Asentajankatu 6
FI-00880 Helsinki
FINLAND

Re: K093590
Trade/Device Name: Planmeca Promax 3D Max
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: April 9, 2010
Received: April 12, 2010

Dear Mr. Moring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093590

Device Name: Planmeca Promax 3D Max

Indications For Use:

Planmeca Promax 3D Max, is a three dimensional Cone Beam Volumetric Tomography (CBVT) x-ray system, which is intended to produce three-dimensional images of the human teeth, jaw and skull. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. The device is to be operated and used by dentists and other legally qualified health care professionals.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ ODD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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